Let's reappraise recruiting South Asians to clinical trials

PERSONAL VIEW **Brian D Gammon, Ashan Gunarathne**

Despite a policy of inclusiveness in health care, the United Kingdom has made little progress in improving overall health among marginalised groups (http://hcna.radcliffe-oxford.com/bemgframe.htm). There is a pressing need for clinical studies among South Asian, black, and other ethnic minority groups to aid the development of targeted strategies to prevent cardiovascular disease. A 1991 study, for example, showed that South Asians—then 4% of the total UK population—bore a disproportionately high burden of mortality from coronary heart disease and stroke (*BMJ* 1991;9:560-4). Health issues associated with the ageing of Britain's ethnic minority population mean that new policy initiatives are urgently needed. Despite this urgency, however, this group is very rarely the focus of clinical investigations to prevent the adverse consequences of this disease burden.

The reasons often given for South Asians' lack of access to clinical trials include language difficulties, poorer access to health care, deprivation, alleged institutional discrimination, and a lack of cross cultural understanding and cultural competence (*Nurs Inq* 2006;13:23-32). The South Asian population in the West Midlands, for example, is mainly clustered in inner city areas such as Sandwell and Walsall, where all indices of social deprivation are above the upper quintile in most electoral wards. Between 20% and 25% of people in these areas are black or South Asian, including Bangladeshi (1.2%), Indian (9.1%), and Pakistani (3%) people. Educational achievement is limited, with between 34% and 54% of people reporting no educational qualification. Pakistani and Bangladeshi people are among the lowest reporters of "fair to good health" and among the most likely to have long term illnesses.

Of the trials listed in the national research register (www.nrr.nhs.uk) only 87 (less than 0.1%) involved South Asians, of which 32 were quantitative and 52 were qualitative, while three were evaluations of existing trials. Thirty nine of these 87 trials (45%) involved only South Asians. Six of the 87 (7%) were randomised controlled trials, and only one of these exclusively involved South Asians and looked at outcome reduction in cardiovascular disease. As randomised controlled trials are seen as the best way to obtain unbiased data, the paucity of trials involving this ethnic group inevitably prejudices the validity of their findings, limiting the usefulness of epidemiological and outcome data.

It should not be assumed that reluctance is due to ethnicity, levels of deprivation, literacy, or cultural difference

In our experience of engaging potential South Asian participants in trials (experience mirrored by others (*Health Technol Assess* 2004;8:1-109)), salient points emerge. Firstly, the arbitrary exclusion of potential participants according to outdated concepts of ethnicity may be exacerbated by researchers' entrenched attitudes. Language differences, for example, need not be a problem, as long as funding is available for the provision of interpreters. Secondly, we have found it to be untrue that such participants fail to understand the research process: they will, as long as enough time and organisational support are available. Thirdly, many South Asian participants enter trials because they think that they will be better able to take part in treatment decisions or that they will gain access to a wider range of services. Fourthly, South Asian trial participants often seem to be passive in healthcare decision making, abrogating responsibility to other family members (*Ethn Dis* 2005;15:548-54), or to profess a determinist outlook or religious fatalism or ascribe happenings to chance. A belief among South Asians that clinical trials are a form of experimentation may also affect their desire to participate in trials.

Furthermore, although South Asians are unlikely to ignore Western drugs in favour of traditional treatments, they are likely to turn to other remedies if they see Western medicine as failing to result in a cure (as with placebos). Thwarted expectations concerning the effect of drugs is one of the main reasons for people dropping out of trials after randomisation. Finally, sufficient thought should be given to protocol design, particularly to frequency of investigative procedures, education about side effects, and the time allotted for each visit, which should allow for the unhurried exchange of information.

The seeming reluctance of South Asians and members of other ethnic minority groups to participate in clinical trials, as evidenced by their low representation, is multifactorial and is part of a complex decision making process. It should not be assumed that reluctance is due to ethnicity, levels of deprivation, literacy, or cultural difference. Such assumptions mean that the development of specific, targeted intervention programmes will be considerably delayed (*N Engl J Med* 2003;348:1170-5).

Although here we have discussed the issue of recruitment and retention of people from ethnic minorities in individual trials, a broader issue is the relatively small number of trials involving South Asians, particularly in cardiovascular research. More research is needed to discover how these issues are related. Barriers to a more inclusive programme of research must be overcome, and this requires inventiveness, flexibility, rigorous planning, and the proper estimation and provision of funds to enable the recruitment of marginalised group members such as South Asians. This will enable a much fuller understanding of the genetic and environmental variables in illness.

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REVIEW OF THE WEEK

Secrets and lies

An award winning film portrays the political dangers and serious health risks faced by women seeking abortions in Ceauşescu's Romania, writes **Khalid Ali**

4 months, 3 weeks & 2 days
A film directed by Cristian Mungiu, Romania 2007
UK release date: 11 January 2008
Rating: ★★★★

Tackling the sensitive issue of illegal abortion, director Cristian Mungiu tells the story of two young women in Ceaușescu's 1980s communist Romania. The film received critical acclaim on the international circuits and won the Palme d'Or at Cannes film festival last year.

Set in 1987, the story follows two close friends living in a dormitory, one of whom, Gabita (Laura Vasiliu), falls pregnant, while the other, Otilia (Anamaria Marinca), tries to help her get an abortion. The film follows the two desperate women over the course of a night, from when they secretly book a hotel room and during their negotiations over the price of procuring the abortion with a mysterious man (Mr Bebe), right through until the following morning.

The abortionist is a cold blooded, exploitative dealer (a real criminal, far from the sensitive, good natured mother figure in Mike Leigh's *Vera Drake* (*BMJ* 2004;329:1107) who knows that the two women are at his mercy. Septic abortion and death from uncontrolled bleeding are risks they have to accept. The clinical details of the procedure appear cold and violent, and lacking basic hygiene. All dealings are cloaked in secrecy to avoid detection. And while the abortion is taking place, Romanian secret police officers lurk in the hotel lobby.

The harsh realities of the oppressive regime and the disintegration of the social support network are brilliantly observed when Otilia goes to her boyfriend's party, leaving her vulnerable friend with no one to help her. Otilia tells her boyfriend the truth, but discovers that he does not approve of abortion. She is shocked, realising that should she become pregnant she could easily end up in the same boat as Gabita and have to rely on illegal abortion.

After Gabita's termination, Otilia has to get rid of the aborted fetus in the dark, deserted streets of Romania. The catastrophic significance of what has happened is etched on her face. By the morning the stress of the night has taken its toll on the two women and they are two crushed human beings. After such a harrowing experience, can they ever again be the same young women they once were, full of the hope of having a normal family life?

It seems clear where the film's sympathies lie—critical of the Romanian government's motives and condemnatory of a healthcare system that could keep quiet in the face of such oppression of women's rights. And whatever viewers' own convictions about abortion, they are likely to wonder how what Gabita and Otilia go through could happen in the modern world.

How can what Gabita and Otilia (pictured) go through happen in the modern world?

Abortion was a criminal offence in Romania from 1966 until 1989. Women and doctors undergoing and performing abortions faced lengthy jail sentences: illegal induced abortion was punishable by up to 12 years' imprisonment and self induced abortion by six months to two years. At that time Romania had a policy of increasing the country's population, and set up special units within the state security police to combat abortion, imposed special taxes on single and childless couples, and introduced compulsory gynaecological examinations in schools. This all led to the emergence of a black market dealing in abortion as if it were any other smuggled good. Ironically, Romania had one of the highest abortion rates in Europe (78 out of 1000 women aged 15-44 had one), and one of the highest maternal mortality rates (150 maternal deaths per 100 000 live births), and there were thousands of unwanted children in institutions.

4 months, 3 weeks & 2 days acts as a commentary on a political regime and a social system that sacrificed its people to a dictator's tyranny. It renews the debate about the legality of abortion, women's rights, and the role of the state in governing procreation and freedom of conception. As unsafe abortion rises to pandemic proportions in developing countries (*Lancet* 2006;368:1908-19), serious steps are needed to stop this tragedy. It is high time that doctors stand up and get involved in policy making to help end such human loss and suffering.

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The state of education

FROM THE FRONTLINE
Des Spence

I swivelled our student flat's television aerial (a wire coat hanger) and called the Sunday evening odds: "*Songs of Praise*, *Poldark*, *David Copperfield* episode 65 (will it ever end?), or *That's Life*? Sod it, let's play cards." Always the evenings descended into argument: Northern Ireland, the class divide, what to do with "swots," education. We were even split educationally, from Catholic, grammar, English public, and (me) comprehensive schools. Like most reasoned discussions these ended in wrestling on the floor, a head lock, and a squealed surrender. Nothing is more likely to cause a fight among doctors than private education, not even pay.

Some 10% of children in Britain attend fee paying schools, and I warrant that the figure is much higher in medical families. As I look at the exhausted faces of colleagues who loiter with intent at weekends and evenings desperately trying to fit in extra work to cover the cost of school fees, I wonder, why bother? Especially these days, as medical school admission panels seem to positively discriminate against applicants from private schools. It is also easy to sneer—the blazers, the ballet lessons, the parents arriving in their four wheel drive vehicles, the mixing with the children of Labour MPs and liberal newspaper editors, the sheer snobbery of it all—but this is just vitriol. What motivates most doctors is an earnest belief they are doing the best for their kids, because independent schools are "better."

I question this assumption. Well structured comprehensive schools with streamed classes and support for pupils of all abilities have a similar academic performance (especially in affluent areas) to many private schools. But education is not just about narrow academic performance. We live in divisive times, and recent mass immigration has further destabilised many communities. Comprehensives scrum down children from divergent backgrounds, broadening their views and giving them a direct appreciation of different classes, religions, and ethnicities. Educating children together offers the greatest hope of cohesion and reduces the risk of the educational and social segregation of the past. Doctors are important opinion leaders in their communities, and our influence is needed in the comprehensive system to drive up standards and show our tradition of tolerance.

My children will attend a state comprehensive because I earnestly believe it is in their best interests. I suspect that I may have to wrestle someone at the next dinner party, though.

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A winter's tale

THE BEST MEDICINE
Liam Farrell

It must be tough being an emperor penguin; not only are you being constantly harassed by film crews, who love the fact that you can't fly away or strafe them with guano, but Morgan Freeman is always popping up from behind an iceberg and global warming is increasingly degrading your breeding grounds and food supplies.

And global warming is no picnic for general practitioners either; it has irrevocably altered the aesthetic of wintertime home visits, a cherished part of general practice since the day Asclepius first said, "Art thou sure thou can't come in to the surgery?"

Gone forever are the days of snowcovered hills, frost coldly riming the meadows, rich beds and bright fires and hot whiskeys, big mugs of tea and freshly baked scones, what Ratty and his little furry life-partner, before coming out of the closet, would have called midwinter's homely comforts. House calls then were a wonderland, like being in a Disney movie starring Dr Finlay and James Herriot, and getting jiggy with Julie Andrews by the final credits.

But now all is utterly changed; it's just mud and misery from October to April.

So instead of tapdancing through the farmyard on a crisp magical white carpet of freshly fallen snow, I was in muck to the knees, and it wasn't just non-organic muck; the mandatory herd of cows had added their enthusiasm to the mix, the result being a cocktail of steaming malodorous ordure that would have given even the mighty Hercules pause for thought; "Not more bloody cows," he'd have said.

I squelched to the door.

"Now is the winter of our discontent made summer by this glorious . . . " I began, as a bit of scholarship always goes down well with our stout yeomanry, but I was interrupted; the usual warm Irish welcome had become, with bitter irony, much colder.

"Are you the f***ing doctor?" I was asked.

I was slightly taken aback, so I explained carefully that I was just the ordinary doctor; to be a f***ing doctor required a further qualification, many years of arduous postgraduate study at Cambridge University culminating in a demanding final examination in which the most critical element was, for obvious reasons, the oral, after which you were awarded a magnificent diploma and a jar of antifungal foot cream.

Patient confidentiality forbids me describing the consultation which followed; suffice to say it was short and concluded with a prescription for antibiotics, just to show How Much I Care. Global warming or not, some things never change.

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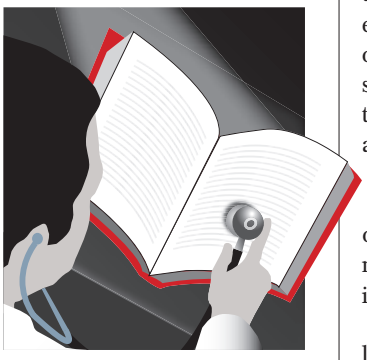
Where egos dare

BETWEEN THE LINES
Theodore Dalrymple



The odd thing about the book is that its conclusions could have been reached if Freud had never seen a single patient

Freud's detractors, who are perhaps now more numerous than his disciples, consider that he played fast and loose with the evidence, and founded a quasi-religious sect in which he used anathema and denunciation of heresy rather than argument to maintain his priestly control. Yet even they are constrained to admire him as a writer; and no fair-minded person could deny him the status of highly cultivated and well educated man, of the kind that is rarely to be encountered nowadays.

Of all his books, *Civilization and Its Discontents* is the one that is most likely to draw the praise of non-Freudians. Published in 1930, not long before the European and world cataclysm, it tells us that civilisation, while necessary, has its price: that of the frustration of our instinctual drives, both sexual and aggressive. We develop an internal watchdog, the superego, that acts as our father once acted if we disobeyed him, by withdrawal of his love and approval. In fact, our conscience can punish us more mercilessly than any parent, or at least any parent who is benign. But there is no final victory of the superego over the id.

When reading Freud, one cannot help recalling Doctor Johnson's famous criticism of a book sent him for his opinion: your book is both true and original, said the great man, but the part that is true is not original, and the part that is original is not true. As it happens, Doctor Johnson himself, in his great philosophical fable *Rasselas*, had demonstrated, with greater elegance and clarity than Freud, the fact (for such I take it to be) that human life is inseparable from dissatisfaction, and that perfect happiness is nowhere to be found. There is therefore no single best way to live.

Freud tells us that there are various methods of dealing with the frustrations consequent upon civilisation, but none of them is entirely satisfactory. Intellectual sublimation, for example, is available only to a relatively small proportion of the population and, as everyone knows, intellectuals are not destined for a life of unalloyed happiness untormented by instinctual desires.

Freud was resolutely anti-utopian, for example rejecting entirely the supposition, popular at the time among intellectuals, that all human unhappiness, and indeed wickedness, was the consequence of the institution of private property, and that once private property had been abolished in its totality, therefore, all would go well with mankind. He knew this was eyewash.

In his derision of those who imagine that Man's passage through life can be made, by some arrangement or other, to resemble that of a hot knife through butter, in which only humanitarian sentiment will reign, Freud tells a wonderful story of a debate in the French National Assembly about the abolition of the death penalty. An abolitionist made an impassioned humanitarian plea, greeted with much applause, until a voice from the floor shouted, "Que messieurs les assassins commencent!" (Let the murderers give up first!) It is not that Freud was in favour of the death penalty; it is just that he did not believe in unalloyed human benevolence, free of all taint of aggression and other disreputable drives or emotions.

The odd thing about the book is that its conclusions could have been reached if Freud had never seen a single patient. But then the relation between his patients and his conclusions was always a rather tenuous one.

Theodore Dalrymple is a writer and retired doctor

MEDICAL CLASSICS

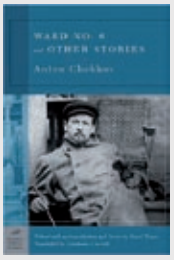
Ward No 6 By Anton Chekhov

First published in 1892

The hero, or rather antihero, of Anton Chekhov's short story "Ward No 6" is Dr Andrey Yefimitch Ragin. He is put in charge of a provincial hospital where the stench and overcrowding would make even the most squalid NHS hospital seem a haven of salubrity. He begins work with zeal and vigour but gradually becomes worn down by the "monotony and obvious uselessness" of the work.

His life changes when he admits Ivan Dmitritch Gromov, an intelligent young man with paranoid delusions, to the almost forgotten ward 6, which is housed in a small lodge in the hospital yard. It consists of one room with five mentally disordered inmates under the supervision of a warder, Nikita, who beats them regularly. Dr Ragin stops going to the hospital daily but begins visiting ward 6. Here he has spirited discussions with Gromov in which he defends a version of stoicism, according to which the external world, which stirs up our emotions, is insignificant, and what is good resides within us: "One must strive for the comprehension of life, and in that is true happiness," says Ragin. Pain can be dismissed by a mere effort of will. But Gromov is not impressed. "Have you any idea of suffering?" he asks. "Were you ever thrashed in your childhood?" Ragin admits that he wasn't.

Ragin is assigned an assistant, Dr Khobotov, who covets Ragin's post and starts to scheme against him.



A committee of local doctors is convened, interviews Ragin, and concludes, on virtually no evidence, that he is mad and suggests that he go on holiday. When he returns he finds that his job has been taken by Khobotov. Ragin has no savings and is now almost destitute. Duped and abandoned by the world he scorned, he colludes in his admission to ward 6. The stoic indifference to external circumstances that he once advocated now fails to give him any consolation. Gromov's ironic advice is to take it philosophically. Outraged by his incarceration, Ragin tries to leave but is struck down by the warder. He falls unconscious on to his bed and dies the next day of a stroke.

Lenin is said to have claimed that it was reading Chekhov's story that turned him into a revolutionary. If true, this is a striking example of how a work of fiction can change the world of facts. The committal of the disillusioned, lazy, but perfectly sane Ragin to a psychiatric ward eerily foreshadows the Soviet practice of diagnosing critics of the regime as "mentally ill" and imprisoning them in psychiatric institutions.

This story is charged with such dense energy that I suspect it contains a great deal of Chekhov himself: his doubts about his own usefulness as a doctor; the tension between a sense that life is meaningless and a simultaneous desire to embrace life, with all its pain; a fear of the solitude required of a writer; and a fear that this solitude might cut him off from life itself.

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